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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/927,315	08/10/2001	Charles S. Zuker	02307E-120110US	4699

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EXAMINER	
BRANNOCK, MICHAEL T	
ART UNIT	**PAPER NUMBER**
1646	

DATE MAILED: 03/10/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.	Applicant(s)
09/927,315	Ryba et al.
Examiner	**Art Unit**
Michael Brannock	1646

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☒ Responsive to communication(s) filed on *Sep 3, 2002* .

2a) ☐ This action is **FINAL.** 2b) ☒ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) *1-54* is/are pending in the application.

4a) Of the above, claim(s) _____ is/are withdrawn from consideration.

5) ☐ Claim(s) _____ is/are allowed.

6) ☐ Claim(s) _____ is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☒ Claims *1-54* are subject to restriction and/or election requirement.

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) ☐ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____ .
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

a) ☐ The translation of the foreign language provisional application has been received.

15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____
4) ☐ Interview Summary (PTO-413) Paper No(s). _____
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

Election/Restriction

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-6, 13, 14, drawn to T1R3 polypeptides, classified in class 530, subclass 350.

II. Claims 7-9, 15, drawn to T1R3/T1R1 heteromeric polypeptides, classified in class 530, subclass 402.

III. Claims 10-12, 16, drawn to T1R3/T1R2 heteromeric polypeptides, classified in class 530, subclass 402.

IV. Claims 17-23, drawn to antibodies, classified in class 530, subclass 388.22.

V. Claims 24-27, 30, 34-48, drawn to methods of assaying for compounds that produce a functional effect on T1R3 polypeptides, classified in class 435, subclass 7.21.

VI. Claims 28, 29, 52-54, drawn to methods of assaying for compounds that produce a functional effect on T1R3/T1R1 heteromeric polypeptides, classified in class 435, subclass 7.21.

VII. Claims 31, 32, 33, 49-51, drawn to methods of assaying for compounds that produce a functional effect on T1R3/T1R1 heteromeric polypeptides, classified in class 435, subclass 7.21.

2. The inventions are distinct, each from the other because of the following reasons:

3. Invention of Group I is related to each of the inventions of Group II and III as mutually exclusive species in an intermediate-final product relationship. Distinctness is proven for claims in this relationship if the intermediate product is useful to make other than the final product (MPEP § 806.04(b), 3rd paragraph), and the species are patentably distinct (MPEP § 806.04(h)). In the instant case, the intermediate product is deemed to be useful to produce antibodies specific to a T1R3 receptor and the inventions are deemed patentably distinct since there is nothing on this record to show them to be obvious variants. Further, the skilled artisan would expect that the intermediate product would lose its particular functional identity, e.g. specific signaling properties, as part of the complex with T1R2 (MPEP § 806.04(b). Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions anticipated by the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Although there are no provisions under the section for "Relationship of Inventions" in M.P.E.P. § 806.05 for inventive groups that are directed to different products, restriction is deemed to be proper because these products appear to constitute patentably distinct inventions for the following reasons: The protein and protein complexes of Groups I-III and the antibodies of Group IV are directed to products that are distinct both physically and functionally, and are not required one for the other, and are therefore patentably distinct. The proteins of Groups I-III can

be used in materially different methods other than to make the antibodies of Group IV, such as in diagnostic methods (e.g. in the methods of Groups V-VII). The antibodies of Group IV can be obtained through expression of the DNA encoding the protein of Groups I-III and can be used ways other than to isolate the protein of Group I, such as in immunohistochemical and diagnostic uses. Further, the polypeptide complexes of Groups II and III are independent and patentably distinct form each other because one is not required for the use of the other.

The polypeptides of Groups I-III are related to the methods of Groups V-VII as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the polypeptides of Groups I-III are patentably distinct from each of the methods of Groups V-VII because the polypeptides can be used in ways that are materially and functionally different than each of the methods such as to produce the antibodies of Group IV.

The antibodies of Group IV are related to the methods of Groups V-VII as product and process of use. In the instant case the antibodies of Group IV are patentably distinct from each of the methods of Groups V-VII, because the antibodies can be used in ways that are materially and functionally different than each of the methods such as in immunohistochemical analysis.

Although there are no provisions under the section for "Relationship of Inventions" in M.P.E.P. § 806.05 for inventive groups that are directed to different methods, restriction is

deemed to be proper because these methods appear to constitute patentably distinct inventions for the following reasons: Groups V-VII are directed to methods that are distinct both physically and functionally, and are not required one for the other. Group V requires an assay of monomeric T1R3 receptor activity, which is not required by any of the other groups. Group VI requires an assay of T1R3/T1R1 receptor activity, which is not required by any of the other groups. Group VII requires assay of T1R3/T1R2 receptor activity, which is not required by any of the other groups.

Therefore, because these inventions are distinct for the reasons given above and because a search and examination of all the groups in one patent application would result in an undue burden, since the searches for the groups are not co-extensive, the classification is different, and the subject matter is divergent, restriction for examination purposes as indicated is proper.

4. Claims 1-6, 13, 14, 17-27, 30, 34-348 are generic to a plurality of disclosed patentably distinct species of inventions, each relating to a particular T1R3 (SEQ ID NO: 15, 20, 23, or 25). Each invention is patentably distinct, the use of one not being required for the use of any other. Each SEQ ID NO represents a structurally and functionally distinct molecule, and although a search of one SEQ ID NO may overlap that of another, no two searches would be coextensive, and nor could one search be relied upon to provide art that is anticipatory or might render obvious any other SEQ ID NO. To search all species of invention in a single application would be unduly burdensome. If either of Group I, IV or V is elected, then Applicant is required under

35 U.S.C. 121 to additionally elect a single disclosed species, such species consisting of single SEQ ID NO designating a particular T1R3 protein.

5. Claims 7-12, 15, 18-23, 28, 29, 31-33, 49-54 are generic to a plurality of disclosed patentably distinct species of inventions, each relating to a particular T1R3 (SEQ ID NO: 15, 20, 23, or 25) and either a T1R1 polypeptide (SEQ ID NO: 1, 2, 3) or a T1R2 polypeptide (SEQ ID NO: 7, 8, 9). Each invention is patentably distinct, the use of one not being required for the use of any other. Each SEQ ID NO represents a structurally and functionally distinct molecule, and although a search of one SEQ ID NO may overlap that of another, no two searches would be coextensive, and nor could one search be relied upon to provide art that is anticipatory or might render obvious any other SEQ ID NO. To search all species of invention in a single application would be unduly burdensome. If either of Group II-III, IV, VI or VII is elected, then Applicant is required under 35 U.S.C. 121 to additionally elect a single disclosed species, such species consisting of a single pair of SEQ ID NOs that is appropriate for that Group. For example, SEQ ID NO: 15 and SEQ ID NO: 3 represent a single disclosed species of invention comprising the human T1R3/T1R1 receptor, and are appropriate for either Group II, IV or VI.

6. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

7. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

8. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Brannock, Ph.D., whose telephone number is (703) 306-5876. The examiner can normally be reached on Mondays through Thursdays from 8:00 a.m. to 5:30 p.m. The examiner can also normally be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler, Ph.D., can be reached at (703) 308-6564.

Official papers filed by fax should be directed to (703) 308-4242. Faxed draft or informal communications with the examiner should be directed to (703) 308-0294.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

MB

February 24, 2003

YVONNE EYLER, PH.D
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600